Aukerman Co. v. R.L. Chaides Const. Co., 960 F.2d 1020, 22 USPQ2d 1321 (Fed.Cir. 1992) (in banc), of the double-bursting bubble "presumption." That "presumption" had no warrant in law, and makes little sense. *See id.* at 1046–47, 22 USPQ2d at 1339–40 (Plager, J., concurring in part and dissenting in part). Cases like this may hasten the day when we discard it in favor of simplification of the law.

Yoshihiro FUJIKAWA, Mikio Suzuki, Hiroshi Iwasaki, Mitsuaki Sakashita and Masaki Kitahara, Appellants,

v.

Sompong WATTANASIN, Appellee. (Two Cases).

Nos. 95–1418, 95–1425.

United States Court of Appeals, Federal Circuit.

Aug. 28, 1996.

Patent interference proceeding was brought. The Board of Patent Appeals and Interferences of the United States Patent & Trademark Office awarded priority of invention to junior party, and senior party appealed. The Court of Appeals, Clevenger, Circuit Judge, held that: (1) in vitro and in vivo tests established practical utility for compound and method counts; (2) junior party did not suppress or conceal invention; and (3) senior party was not entitled to add subgenus count to interference.

Affirmed.

1. Patents ⇐46, 98

Patent may not be granted to invention unless substantial or practical utility for invention has been discovered and disclosed.

2. Patents ⇐46, 90(5)

Actual reduction to practice, which constitutes in law the final phase of invention for which patent is sought, cannot be established absent showing of practical utility.

3. Patents ⇐14, 49

In pharmaceutical arts, practical utility of compound for which patent is sought may be shown by adequate evidence of any pharmacological activity.

4. Patents ⇐49

To show practical utility of novel pharmacological compound for which patent is sought, there must be sufficient correlation between tests and asserted pharmacological activity so as to convince those skilled in the art, to a reasonable probability, that compound will exhibit asserted pharmacological behavior.

5. Patents ⇐114.22, 114.25

Ultimate determination of reduction to practice of invention for which patent is sought is a question of law that Court of Appeals reviews de novo.

6. Patents ⇐114.25

Court of Appeals reviews factual findings supporting legal conclusions of Board of Patent Appeals and Interferences about reduction to practice for clear error.

7. Patents ⇐114.22

Whether practical utility has been established for novel compound for which patent is sought is a question of fact.

8. Patents ⇐90(5)

In vitro tests of compounds for inhibiting cholesterol biosynthesis established practical utility of compound genus; several compounds exhibited activity in vitro, and experts indicated that in vitro test results convinced them that claimed compounds would exhibit desired pharmacological activity when administered in vivo.

9. Patents ⇐90(5)

Method of inhibiting biosynthesis of cholesterol by administering compound was reduced to practice when successful in vivo testing of compound was completed, even though one anomaly in test data showed that

compound's potency was less at higher dosage than at lower dosage.

10. Patents ⇐114.25

Suppression or concealment of invention for which patent is sought is a question of law that Court of Appeals reviews de novo. 35 U.S.C.A. § 102(g).

11. Patents ⇐90(1)

"Intentional suppression" of invention for which patent is sought refers to situations in which inventor designedly, and with view of applying it indefinitely and exclusively for his own profit, withholds his invention from public. 35 U.S.C.A. § 102(g).

See publication Words and Phrases for other judicial constructions and definitions.

12. Patents ⇐90(1)

"Intentional suppression" of invention for which patent is sought requires more than passage of time; it requires evidence that inventor intentionally delayed filing in order to prolong period during which invention is maintained in secret. 35 U.S.C.A. § 102(g).

13. Patents ⇐90(5), 97

Inventor of compound and method for inhibiting cholesterol biosynthesis did not intentionally suppress or conceal invention; all indications were that throughout period between reduction to practice and filing of patent application, inventor moved slowly but inexorably toward disclosure. 35 U.S.C.A. § 102(g).

14. Patents ⇐91(.5)

Evidence that first inventor was spurred to disclose by activities of a second inventor is an important factor in determinations of patent priority. 35 U.S.C.A. § 102(g).

15. Patents ⇐97

Circumstances surrounding first inventor's delay in filing for patent and reasonableness of that delay are important factors that must be considered in deciding questions of suppression or concealment. 35 U.S.C.A. § 102(g).

16. Patents ⇐97

Inference of suppression or concealment of compound and method for inhibiting cholesterol biosynthesis in humans and other animals was not warranted, despite delay of seventeen months between reduction to practice and filing for patent; subject was complex, inventor moved slowly toward filing application, and unexplained period of delay was only three months. 35 U.S.C.A. § 102(g).

17. Patents ⇐90(5)

Inventor's reduction to practice of compound for inhibiting cholesterol biosynthesis, which was followed by period of inactivity, did not bar him from relying on his earliest date of renewed activity for purposes of priority of patent applications. 35 U.S.C.A. § 102(g).

18. Patents ⇐99

Whether disclosure contains a sufficient written description to support addition of proposed count in patent interference proceeding is a question of fact that Court of Appeals reviews for clear error. 35 U.S.C.A. § 112.

19. Patents ⇐99

Ipsis verbis disclosure is not necessary to satisfy written description requirement of statute governing patent specifications; instead, disclosure need only reasonably convey to persons skilled in the art that inventor had possession of subject matter in question. 35 U.S.C.A. § 112.

20. Patents ⇐106(2)

Senior party was not entitled to add sub-genus count to patent interference in proceeding pertaining to compound and method for inhibiting cholesterol biosynthesis; senior party's proposed count was not disclosed ipsis verbis in junior party's application, and one of ordinary skill in the art would not have been directed by junior party's application to senior party's proposed sub-genus count. 35 U.S.C.A. § 112.

Steven B. Kelber, Oblon, Spivak, McClelland, Maier & Neustadt, P.C., Arlington, Virginia, argued, for appellants.

Diane E. Furman, Sandoz Corporation, East Hanover, New Jersey, argued, for appellee.

Before MAYER, CLEVENGER, and RADER, Circuit Judges.

CLEVENGER, Circuit Judge.

Yoshihiro Fujikawa et al. (Fujikawa) appeal from two decisions of the Board of Patent Appeals and Interferences of the United States Patent & Trademark Office (Board) granting priority of invention in two related interferences to Sompong Wattanasin, and denying Fujikawa's motion to add an additional sub-genus count to the interferences. We affirm.

I

These interferences pertain to a compound and method for inhibiting cholesterol biosynthesis in humans and other animals. The compound count recites a genus of novel mevalonolactones. The method count recites a method of inhibiting the biosynthesis of cholesterol by administering to a "patient in need of said treatment" an appropriate dosage of a compound falling within the scope of the compound count.

The real parties in interest are Sandoz Pharmaceuticals Corporation (Sandoz), assignee of Wattanasin, and Nissan Chemical Industries, Ltd. (Nissan), assignee of Fujikawa.

The inventive activity of Fujikawa, the senior party, occurred overseas. Fujikawa can thus rely only on his effective filing date, August 20, 1987, to establish priority. 35 U.S.C. § 102(g) (1994). Whether Wattanasin is entitled to priority as against Fujikawa therefore turns on two discrete questions. First, whether Wattanasin has shown conception coupled with diligence from just prior to Fujikawa's effective filing date until reduction to practice. *Id.* Second, whether Wattanasin suppressed or concealed the invention between reduction to practice and filing. *Id.* With respect to the first question, Fujikawa does not directly challenge the Board's holdings on Wattanasin's conception or diligence, but rather contends that the Board incorrectly fixed the date of Wattanasin's reduction to practice. As for the second question, Fujikawa contends that the Board erred in concluding that Wattanasin had not suppressed or concealed the invention. Fujikawa seeks reversal, and thus to establish priority in its favor, on either ground.

II

The Board divided Wattanasin's inventive activity into two phases. The first phase commenced in 1979 when Sandoz began searching for drugs which would inhibit the biosynthesis of cholesterol. Inventor Wattanasin was assigned to this project in 1982, and during 1984–1985 he synthesized three compounds falling within the scope of the compound count. When tested *in vitro*, each of these compounds exhibited some cholesterol-inhibiting activity, although not all the chemicals were equally effective. Still, according to one Sandoz researcher, Dr. Damon, these test results indicated that, to a high probability, the three compounds "would be active when administered *in vivo* to a patient to inhibit cholesterol biosynthesis, i.e. for the treatment of hypercholesteremia or atherosclerosis." Notwithstanding these seemingly positive results, Sandoz shelved Wattanasin's project for almost two years, apparently because the level of *in vitro* activity in two of the three compounds was disappointingly low.

By January 1987, however, interest in Wattanasin's invention had revived, and the second phase of activity began. Over the next several months, four more compounds falling within the scope of the compound count were synthesized. In October, these compounds were tested for *in vitro* activity, and each of the four compounds yielded positive results. Again, however, there were significant differences in the level of *in vitro* activity of the four compounds. Two of the compounds in particular, numbered 64–935 and 64–936, exhibited *in vitro* activity significantly higher than that of the other two compounds, numbered 64–933 and 64–934.

Soon after, in December 1987, the three most active compounds *in vitro* were subjected to additional *in vivo* testing. For Sandoz, one primary purpose of these tests was to

determine the *in vivo* potency of the three compounds relative to that of Compactin, a prior art compound of known cholesterol-inhibiting potency. From the results of the *in vivo* tests, reproduced in the margin,[1] Sandoz calculated an ED_{50}[2] for each of the compounds and compared it to the ED_{50} of Compactin. Only one of the compounds, compound 64–935, manifested a better ED_{50} than Compactin: an ED_{50} of 0.49 as compared to Compactin's ED_{50} of 3.5. All of the tests performed by Sandoz were conducted in accordance with established protocols.

During this period, Sandoz also began to consider whether, and when, a patent application should be filed for Wattanasin's invention. Several times during the second phase of activity, the Sandoz patent committee considered the question of Wattanasin's invention but decided that it was too early in the invention's development to file a patent application. Each time, however, the patent committee merely deferred decision on the matter and specified that it would be taken up again at subsequent meetings. Finally, in January 1988, with the *in vivo* testing completed, the Committee assigned Wattanasin's invention an "A" rating which meant that the invention was ripe for filing and that a patent application should be prepared. The case was assigned to a Ms. Geisser, a young patent attorney in the Sandoz patent department with little experience in the pharmaceutical field.

Over the next several months the Sandoz patent department collected additional data from the inventor which was needed to prepare the patent application. This data gathering took until approximately the end of May 1988. At that point, work on the case seems to have ceased for several months until Ms. Geisser began preparing a draft sometime in the latter half of 1988. The parties dispute when this preparation began. Fujikawa contends that it occurred as late as October, and that Ms. Geisser was spurred to begin preparing the draft application by the discovery that a patent to the same subject matter had been issued to a third party, Picard. Fujikawa, however, has no evidence to support that contention. In contrast, Sandoz contends that Ms. Geisser began the draft as early as August, and that she was already working on the draft when she first heard of Picard's patent. The evidence of record, and in particular the testimony of Ms. Geisser, supports that version of events. In any event, the draft was completed in November and, after several turn-arounds with the inventor, ultimately filed in March of 1989.

Both Wattanasin and Fujikawa requested an interference with Picard. The requests were granted and a three-party interference between Picard, Fujikawa, and Wattanasin was set up. Early in the proceedings, however, Picard filed a request for an adverse judgment presumably because he could not antedate Fujikawa's priority date. What remained was a two-party interference between Fujikawa and Wattanasin. Ultimately, for reasons not significant to this appeal, the interference was divided into two interferences: one relating to the method count and one relating to the compound count. The Board decided each of these interferences adverse to Fujikawa.

With respect to the compound count, the Board made two alternative findings regarding reduction to practice. First, it found that the *in vitro* results in October 1987 showed sufficient practical utility for the compound so as to constitute a reduction to practice as of the date of those tests.[3] In the alterna-

1.

Compound	dosage	% change
64–933	1.0	-36.3%
	0.3	-17.0%
	0.1	-18.6%
64–935	1.0	-65.8%
	0.3	-29.7%
	0.1	-36.3%
64–936	1.0	- 9.0%
	0.3	-39.2%
	0.1	-22.5%

2. The ED_{50} of a compound represents the effective concentration, measured in milligrams of compound per kilogram of laboratory specimen, which inhibits cholesterol biosynthesis by 50%.

3. As explained more fully below, reduction to practice requires a showing of practical utility, which may be satisfied by an "adequate showing of any pharmacological activity." *Nelson v.*

tive, the Board held, the *in vivo* tests which showed significant activity in the 64–935 compound at doses of 1.0 and 0.1 mg were sufficient to show practical utility. Consequently, Wattanasin had reduced the compound to practice, at the latest, as of December 1987. Since Fujikawa did not challenge Wattanasin's diligence for the period between Fujikawa's effective filing date of August 20, 1987 and Wattanasin's reduction to practice in either October or December 1987, the Board held that Wattanasin was *de facto* the first inventor of the compound count. Finally, the Board found that the seventeen month period (counting from the *in vitro* testing) or fifteen month period (counting from the *in vivo* testing) between Wattanasin's reduction to practice and filing was not sufficient to raise an inference of suppression or concealment given the complexity of the invention, and therefore awarded priority of the compound count to Wattanasin. In reaching this conclusion, the Board rejected Fujikawa's argument that Wattanasin was spurred to file by Picard because it held that spurring by Picard, a third party, had no legal effect in a priority dispute between Fujikawa and Wattanasin.

With respect to the method count, the Board determined that Wattanasin reduced to practice in December 1987 on the date that *in vivo* testing of the 64–935 compound was concluded. In reaching that conclusion, the Board first noted that a reduction to practice must include every limitation of the count. Consequently, Wattanasin's early *in vitro* testing could not constitute a reduction to practice of the *method* count, since that count recites administering the compound to a "patient." The *in vivo* testing, however, met the limitations of the count since the word "patient" was sufficiently broad to include the laboratory rats to whom the compounds were administered. The *in vivo* testing also proved that 64–935 had practical utility because the compound displayed significant cholesterol inhibiting activity at doses of 1.0 and 0.1 mg. Given this date of reduction to practice, the Board again held that Wattanasin was the *de facto* first inventor of the count and that the delay in filing of fifteen months was not sufficient to trigger an inference of suppression or concealment. The Board therefore awarded priority of the method count to Wattanasin.

Before this court, Fujikawa seeks review of these adverse priority determinations. In addition, during the motions period of the interference, Fujikawa moved to have an additional sub-genus count added to the interference. The Board denied that motion on the ground that the Wattanasin disclosure did not contain a sufficient written description to support the proposed count. Fujikawa appeals that decision, as well. We have jurisdiction to hear this appeal under 28 U.S.C. § 1295(a)(4)(A) (1994).

III

We first address Fujikawa's argument that Wattanasin's *in vitro* and *in vivo* tests failed to establish a practical utility for either the compound or method count. The Board held that the *in vitro* tests established a practical utility for the compound and that the *in vivo* tests established a practical utility for both the compound and method counts. For the reasons set out below, we affirm these findings of the Board.

[1, 2] For over 200 years, the concept of utility has occupied a central role in our patent system. *See Brenner v. Manson*, 383 U.S. 519, 529, 86 S.Ct. 1033, 1039, 16 L.Ed.2d 69, 148 USPQ 689, 693 (1966). Indeed, "[t]he basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility." *Id.* at 534, 86 S.Ct.at 1042, 148 USPQ at 695. Consequently, it is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed. *See Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 USPQ 739, 742 (Fed.Cir. 1985). Similarly, actual reduction to practice, which constitutes in law the final phase of invention, cannot be established absent a showing of practical utility. *See Blicke v. Treves*, 44 C.C.P.A. 753, 241 F.2d 718, 720–21, 112 USPQ 472, 474–75 (1957).

Bowler, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

[3] In the pharmaceutical arts, our court has long held that practical utility may be shown by adequate evidence of any pharmacological activity. *See, e.g., Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980); *In re Krimmel*, 48 C.C.P.A. 1116, 292 F.2d 948, 952–53, 130 USPQ 215, 219 (1961). For example, in *Campbell v. Wettstein*, 476 F.2d 642, 646–47, 177 USPQ 376, 379 (CCPA 1973) we stated that "[m]oreover, the interference counts contain no limitation relating to intended use or to discovered properties of the claimed compounds. Accordingly, under well-established precedent, evidence establishing substantial utility for any purpose is sufficient to show reduction to practice." The rule in *Campbell* was applied in *Rey–Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 USPQ 453, 454 (CCPA 1974) ("Since the count contains no limitation related to any utility, evidence which would establish a substantial utility for any purpose is sufficient to show its reduction to practice.").[4] Such activity constitutes a practical utility because "[i]t is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility." *Nelson*, 626 F.2d at 856, 206 USPQ at 883; *see also Krimmel*, 292 F.2d at 952–53, 130 USPQ at 219.

[4] It may be difficult to predict, however, whether a novel compound will exhibit pharmacological activity, even when the behavior of analogous compounds is known to those skilled in the art. Consequently, testing is often required to establish practical utility. *See, e.g., Blicke*, 241 F.2d at 720, 112 USPQ at 475. But the test results need not absolutely prove that the compound is pharmacologically active. All that is required is that the tests be "*reasonably* indicative of the desired [pharmacological] response." *Nelson*, 626 F.2d at 856, 206 USPQ at 884. (emphasis added). In other words, there must be a sufficient correlation between the tests and an asserted pharmacological activity so as to convince those skilled in the art, to a reasonable probability, that the novel compound will exhibit the asserted pharmacological behavior. *See Cross*, 753 F.2d at 1050, 224 USPQ at 747.

[5–7] The ultimate determination of reduction to practice is a question of law which we review de novo. *See Holmwood v. Sugavanam*, 948 F.2d 1236, 1238, 20 USPQ2d 1712, 1714 (Fed.Cir.1991). In contrast, we review the Board's factual findings supporting its legal conclusions about reduction to practice for clear error. *Id.* Whether a practical utility has been established for a novel compound is a question of fact. *See Cross*, 753 F.2d at 1044 n. 7, 224 USPQ at 742 n. 7. We therefore review the Board's findings with respect to practical utility for clear error.

A

This court has, on many occasions, considered the type and quantity of testing necessary to establish a practical utility for a novel compound. Although each case of practical utility must be considered on its own facts, *see, e.g., Blicke*, 241 F.2d at 720, 112 USPQ at 475, examination of our precedent illustrates the degree of proof which we have deemed sufficient to establish practical utility in the past.

[8] The facts in this case are substantially similar to those in *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed.Cir.1985). There, we expressly held that, in appropriate circumstances, evidence of *in vitro* testing

4. Strictly speaking, this articulation of the standard (i.e. evidence of *any* pharmacological activity) applies only when the count does not recite a particular utility. *See Rey–Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 USPQ 453, 454 (CCPA 1974). In contrast, when the count recites a particular utility, practical utility requires an adequate showing of the recited utility. In this case, the compound count does not recite a particular utility, and practical utility is thus satisfied by evidence of any pharmacological activity. The method count, however, does recite a particular utility (i.e., cholesterol inhibition in patients in need of such treatment), and practical utility for that count therefore requires an adequate showing of that recited utility.

could adequately establish a practical utility.[5] As we there explained:

> We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question.... [U]nder the circumstances of the instant case, where [an application] discloses an *in vitro* utility, ... and where the disclosed *in vitro* utility is supplemented by the similar *in vitro* and *in vivo* pharmacological activity of structurally similar compounds, ... we agree with the Board that this *in vitro* utility is sufficient to [establish utility].

Id. at 1051, 224 USPQ at 748. Thus, *Cross* holds that positive *in vitro* results, in combination with a known correlation between such *in vitro* results and *in vivo* activity, may be sufficient to establish practical utility.

Fujikawa does not argue that the law as stated in *Cross* is incorrect. Instead, Fujikawa contends that Wattanasin has failed to establish an adequate correlation between *in vitro* and *in vivo* results in the field of cholesterol-inhibiting compounds to permit Wattanasin to rely on affirmative *in vitro* results to establish a practical utility for the compound.

The Board determined that Wattanasin had reduced the compound count to practice in October 1987 when several compounds falling within the scope of the genus count exhibited activity *in vitro*. In reaching that conclusion, the Board relied on testimony from those skilled in the art that the *in vitro* results convinced them that the claimed compounds would exhibit the desired pharmacological activity when administered *in vivo*. This included testimony that "*in vivo* activity is typically highly correlatable to a compound's *in vitro* activity" in this field. The facts in this case are thus analogous to the ones in *Cross* where the court relied on positive *in vitro* test results in combination with a known correlation between such *in vitro* tests and *in vivo* activity to support a finding of practical utility.

To counter the Board's decision, Fujikawa points to the testimony of its own expert, Dr. Holmlund, who testified that:

> there is a reasonable element of doubt that some elements may be encountered which are active in the *in vitro* assay, but yet inactive in the *in vivo* assay.

According to Fujikawa, this testimony establishes that the *in vitro* tests were insufficient to prove practical utility.

We note first that to the extent the record presents a conflict in the testimony, the Board was well within its discretion as fact finder to credit the testimony of Wattanasin's witnesses over that of Fujikawa's. More fundamentally, however, we do not consider Dr. Holmlund's testimony as a whole to contradict the Board's finding. Of course, it is possible that some compounds active *in vitro* may not be active *in vivo*. But, as our predecessor court in *Nelson* explained, a "rigorous correlation" need not be shown in order to establish practical utility; "reasonable correlation" suffices. Here, even Dr. Holmlund implied in the question and answer immediately following the above quoted portion of his testimony, that such a "reasonable correlation" exists:

> Q. Would you accept, subject to exceptions that might occur, that the failure to find [*in vivo*] activity would be considered an exception, that there would be a reasonable expectancy [that *in vitro* activity implies that the compound will be active *in vivo*]?
>
> A. I think I would probably accept that.

Fujikawa also cites two articles[6] which it claims show that there is no reliable relationship between *in vitro* results and *in vivo* results in cholesterol inhibiting compounds similar to the ones at issue in this case. We disagree. Although the Sliskovic article, for

5. While *Cross* involved a constructive reduction to practice, the same general principles are applicable to an actual reduction to practice. *See id.* at 1046 n. 14, 224 USPQ at 744 n. 14.

6. The two articles are D.R. Sliskovic et al, *Inhibitors of Cholesterol Biosynthesis*, 34 J. Med. Chemistry 367 (1991) (Sliskovic); and F.G. Kathawala, *HMG–CoA Reductase Inhibitors: An Exciting Development in the Treatment of Hyperlipoproteinemia*, 11 Medicinal Research Reviews 121 (1991) (Kathawala).

example, teaches that *in vitro* testing is sometimes not a good indicator of how potent a compound will be *in vivo*, it does imply that compounds which are active *in vitro* will normally exhibit some *in vivo* activity. *See* Sliskovic, at 370. Similarly, the Kathawala article expressly states: "For most substances, although not for all, the relative potency determined in *in vitro* microsomal assay against HMG–CoA reductase parallels the *in vivo* activity in rats for the inhibition of 14C-acetate into sterols." Kathawala at 136–37. On these facts, we hold that the Board did not err in finding that Wattanasin's *in vitro* tests established a practical utility for the genus recited in the compound count.

B

[9] Turning to the method count, the Board found that Wattanasin reduced the method to practice in December 1987 when successful *in vivo* testing of the compound was completed. This finding, too, was based on testimony that the *in vivo* data for one of the compounds tested, 64–935, showed significant cholesterol inhibiting activity in the laboratory rats tested.

Fujikawa challenges the Board's holding by referring to an anomaly in the test data of the 64–935 compound which it contends undercuts the reliability of the *in vivo* tests. In particular, Fujikawa points to the fact that the compound's potency was less at a dosage of 0.3 mg than it was at a dosage of 0.1 mg. On the basis of this aberration, Fujikawa's expert, Dr. Holmlund, testified that this test data was unreliable and could not support a finding that the compound was pharmacologically active.

It is clear from the Board's opinion, however, that to the extent Dr. Holmlund was testifying that this aberration would lead one of ordinary skill to completely reject these test results, the Board did not accept his testimony. This decision of the Board was not clear error. Admittedly, the decreased potency at 0.3 mg is curious. The question remains, however, as to how much this glitch in the data would undercut the persuasiveness of the test results as a whole in the mind of one of ordinary skill. Each party presented evidence on this point and the Board resolved this disputed question of fact by finding that the test results as a whole were sufficient to establish pharmacological activity in the minds of those skilled in the art. In doing so, the Board properly exercised its duty as fact finder, and we therefore affirm its finding on this point.[7]

As noted above, Fujikawa does not challenge the Board's conclusions that Wattanasin conceived prior to Fujikawa's effective date or that Wattanasin pursued the invention with diligence from just prior to Fujikawa's date until his reductions to practice in October and December 1987. Consequently, we affirm the Board's finding that Wattanasin has shown conception coupled with diligence from just prior to Fujikawa's effective date of August 20, 1987 up to the date he reduced the invention to practice in October 1987, for the compound, or December 1987, for the method.

IV

Having determined that Wattanasin was the *de facto* first inventor, the remaining question before the Board was whether Wattanasin had suppressed or concealed the in-

7. Before the Board, Fujikawa additionally argued that *in vivo* testing cannot establish reduction to practice of the method count because it does not fulfill every limitation of the count. In particular, Fujikawa argued that only human beings can be considered "patients in need of" cholesterol biosynthesis inhibition, as required by the count. As noted above, the Board rejected this argument and held that the term "patient" in the count is broad enough to encompass mammals, such as the laboratory rats tested *in vivo*.

In its brief to this court, Fujikawa renews this argument. In the process, however, Fujikawa seems to add an additional ground which it did not argue before the Board below. We are not absolutely certain, but it appears that Fujikawa is now contending that *in vivo* testing cannot constitute a reduction to practice because the rats tested were, from all that would appear, healthy animals, rather than animals in need of cholesterol biosynthesis inhibition. To the extent that Fujikawa's argument before this court is directed to this novel ground not raised below, we consider the argument waived and decline to address it. To the extent that Fujikawa is still arguing that the count requires administration of the compound to a human, we disagree, and affirm the Board's decision on this point.

vention between the time he reduced to practice and the time he filed his patent application. Suppression or concealment of the invention by Wattanasin would entitle Fujikawa to priority. 35 U.S.C. § 102(g).

[10] Suppression or concealment is a question of law which we review de novo. *Brokaw v. Vogel*, 57 C.C.P.A. 1296, 429 F.2d 476, 480, 166 USPQ 428, 431 (1970). Our case law distinguishes between two types of suppression and concealment: cases in which the inventor deliberately suppresses or conceals his invention, and cases in which a legal inference of suppression or concealment is drawn based on "too long" a delay in filing a patent application. *Paulik v. Rizkalla*, 760 F.2d 1270, 1273, 226 USPQ 224, 226 (Fed.Cir. 1985) (in banc).

[11–13] Fujikawa first argues that there is evidence of intentional suppression or concealment in this case. Intentional suppression refers to situations in which an inventor "designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public." *Id.* (quoting *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328, 16 L.Ed. 165 (1858)). Admittedly, Sandoz was not overly efficient in preparing a patent application, given the time which elapsed between its reduction to practice in late 1987 and its ultimate filing in March 1989. Intentional suppression, however, requires more than the passage of time. It requires evidence that the inventor intentionally delayed filing in order to prolong the period during which the invention is maintained in secret. *Cf. Peeler v. Miller*, 535 F.2d 647, 653–54, 190 USPQ 117, 122 (CCPA 1976) (implying that intentional suppression requires showing of specific intent). Fujikawa presented no evidence that Wattanasin delayed filing for this purpose. On the contrary, all indications are that throughout the period between reduction to practice and filing, Sandoz moved slowly (one might even say fitfully), but inexorably, toward disclosure. We therefore hold that Wattanasin did not intentionally suppress or conceal the invention in this case.

Absent intentional suppression, the only question is whether the 17 month period between the reduction to practice of the compound, or the 15 month period between reduction to practice of the method, and Wattanasin's filing justify an *inference* of suppression or concealment. *See id.* The Board held that these facts do not support such an inference. As the Board explained: "In our view, this hiatus in time is not sufficiently long to raise the inference that Wattanasin suppressed or concealed the invention considering the nature and complexity of the invention here."

[14] Fujikawa attacks this finding of the Board on two grounds. First, it contends that the Board should not have held that a 15 or 17 month delay is *per se* insufficient to raise an inference of suppression or concealment without examining the circumstances surrounding the delay and whether, in view of those circumstances, Wattanasin's delay was reasonable. Second, Fujikawa argues that the Board failed to consider evidence that Wattanasin was spurred to file by the issuance of a patent to a third party, Picard, directed to the same genus of compounds invented by Wattanasin. Evidence that a first inventor was spurred to disclose by the activities of a second inventor has always been an important factor in priority determinations because it creates an inference that, but for the efforts of the second inventor, "the public would never have gained knowledge of [the invention]." *Brokaw*, 429 F.2d at 480, 166 USPQ at 431. Here, however, the Board expressly declined to consider the evidence of spurring because it held that spurring by a third party who is not a party to the interference is irrelevant to a determination of priority as between Wattanasin and Fujikawa. We first address Fujikawa's arguments concerning spurring.

A

We are not certain that the Board is correct that third party spurring is irrelevant in determining priority. After all, "[w]hat is involved here is a policy question as to which of the two rival inventors has the greater right to a patent." *Brokaw*, 429 F.2d at 480, 166 USPQ at 430. Resolution of this question could well be affected by the fact that one of the inventors chose to maintain his

invention in secrecy until disclosure by another spurred him to file, even when the spurrer was a third party not involved in the interference. We need not resolve that question here, however, because we hold that no reasonable fact finder could have found spurring on the facts of this case. The only evidence in the record on the question of spurring is the testimony of Ms. Geisser who expressly testified that she had already begun work on the Wattanasin draft application before she learned of Picard's patent, in other words, that she had not been spurred by Picard. Consequently, we leave the question of the relevance of third party spurring for another case.

B

[15] Fujikawa's other argument also requires us to examine the evidence of record in this case. As Fujikawa correctly notes, this court has not set strict time limits regarding the minimum and maximum periods necessary to establish an inference of suppression or concealment. *See Correge v. Murphy*, 705 F.2d 1326, 1330, 217 USPQ 753, 756 (Fed.Cir.1983). Rather, we have recognized that "it is not the time elapsed that is the controlling factor but the total conduct of the first inventor." *Young v. Dworkin*, 489 F.2d 1277, 1285, 180 USPQ 388, 395 (CCPA 1974) (Rich, J., concurring). Thus, the circumstances surrounding the first inventor's delay and the reasonableness of that delay are important factors which must be considered in deciding questions of suppression or concealment. *See, e.g., id.* at 1281–82, 180 USPQ at 392–93. Fujikawa again correctly notes that the Board's opinion gives short shrift to the question of whether *this* delay on the facts of *this* case was reasonable. In seeking reversal of the Board's decision, Fujikawa asks us to assess the factual record for ourselves to determine whether Wattanasin engaged in sufficient disclosure-related activity to justify his 17–month delay in filing. The facts of record, however, do not support Fujikawa's position.

[16] In our view, the circumstances in this case place it squarely within the class of cases in which an inference of suppression or concealment is not warranted. We acknowledge, of course, that each case of suppression or concealment must be decided on its own facts. Still, the rich and varied case law which this court has developed over many years provides some guidance as to the type of behavior which warrants an inference of suppression or concealment. *See Paulik*, 760 F.2d at 1280, 226 USPQ at 231–32 (Rich, J., concurring). In this case Wattanasin delayed approximately 17 months between reduction to practice and filing. During much of that period, however, Wattanasin and Sandoz engaged in significant steps towards perfecting the invention and preparing an application. For example, we do not believe any lack of diligence can be ascribed to Wattanasin for the period between October and December 1987 when *in vivo* testing of the invention was taking place. *See Young*, 489 F.2d at 1281, 180 USPQ at 392. Similarly, at its first opportunity following the *in vivo* testing, the Sandoz patent committee approved Wattanasin's invention for filing. This takes us up to the end of January 1988.

Over the next several months, until May 1988, the Sandoz patent department engaged in the necessary collection of data from the inventor and others in order to prepare Wattanasin's patent application. We are satisfied from the record that this disclosure-related activity was sufficient to avoid any inference of suppression or concealment during this period.[8] *Cf. Correge*, 705 F.2d at 1330–31, 217 USPQ at 756 (five significant acts of disclosure-related activity over the course of seven months sufficient to rebut any inference of suppression). Also, as noted above, the record indicates that by August 1988, Ms. Geisser was already at work preparing the application, and that work continued on various drafts until Wattanasin's filing date in March 1989. Thus, the only real period of unexplained delay in this case is the

8. Our conclusion in this regard is based, in small part, on the testimony of Mr. Melvyn Kassenoff, a lawyer in Sandoz's patent department. Before the Board, Fujikawa challenged large parts of this testimony as inadmissible. In this opinion we therefore rely only on those portions of the testimony which even Fujikawa concedes are admissible, i.e., testimony relating to Mr. Kassenoff's legal services rendered in connection with the prosecution of Wattanasin's application.

approximately three month period between May and August of 1988.

Given a total delay of 17 months, an unexplained delay of three months, the complexity of the subject matter at issue, and our sense from the record as a whole that throughout the delay Sandoz was moving, albeit slowly, towards filing an application, we conclude that this case does not warrant an inference of suppression or concealment. Consequently, we affirm the Board on this point.

C

[17] Finally, Fujikawa contends that assuming *in vitro* tests are sufficient to establish reduction to practice, Wattanasin reduced the compound count to practice in 1984 when he completed *in vitro* testing of his first three compounds falling within the scope of the count. If so, Fujikawa argues, the delay between reduction to practice and filing was greater than four years, and an inference of suppression or concealment is justified.[9]

We reject this argument in view of *Paulik v. Rizkalla*, 760 F.2d 1270, 226 USPQ 224 (Fed.Cir.1985) (in banc). In *Paulik*, we held that a suppression or concealment could be negated by renewed activity prior to an opposing party's effective date. There, inventor Paulik reduced his invention to practice and submitted an invention disclosure to his employer's patent department. For four years the patent department did nothing with the disclosure. Then, just two months before Rizkalla's effective date, the patent department allegedly picked up Paulik's disclosure and worked diligently to prepare a patent application which it ultimately filed. *See id.* at 1271–72, 226 USPQ at 224–25. We held that although Paulik could not rely on his original date of reduction to practice to establish priority, he could rely on the date of renewed activity in his priority contest with Rizkalla. In large measure, this decision was driven by the court's concern that denying an inventor the benefit of his renewed activity, might "discourage inventors and their supporters from working on projects that had been 'too long' set aside, because of the impossibility of relying, in a priority contest, on either their original work or their renewed work." *Id.* at 1275–76, 226 USPQ at 227–28.

Paulik's reasoning, if not its holding, applies squarely to this case. A simple hypothetical illustrates why this is so. Imagine a situation similar to the one facing Sandoz in early 1987. A decisionmaker with limited funds must decide whether additional research funds should be committed to a project which has been neglected for over two years. In making this decision, the decisionmaker would certainly take into account the likelihood that the additional research might yield valuable patent rights. Furthermore, in evaluating the probability of securing those patent rights, an important consideration would be the earliest priority date to which the research would be entitled, especially in situations where the decisionmaker knows that he and his competitors are "racing" toward a common goal. Thus, the right to rely on renewed activity for purposes of priority would encourage the decisionmaker to fund the additional research. Conversely, denying an inventor the benefit of renewed activity would discourage the decisionmaker from funding the additional research.

Here, Wattanasin returned to his abandoned project well before Fujikawa's effective date and worked diligently towards reducing the invention to practice a second time. For the reasons explained above, we hold that, on these facts, Wattanasin's earlier reduction to practice in 1984 does not bar him from relying on his earliest date of renewed activity for purposes of priority.

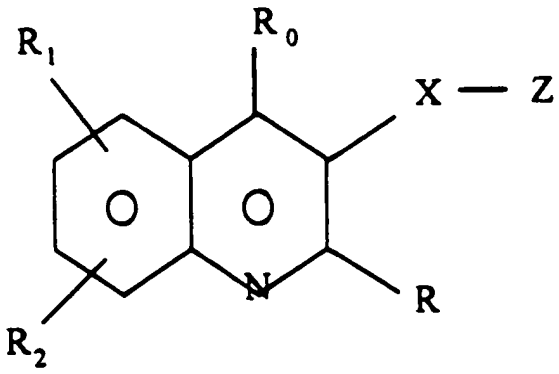
V

[18] Fujikawa also appeals the Board's decision denying Fujikawa's motion to add a sub-genus count to the interference. The Board denied the motion because it found that Wattanasin's disclosure did not sufficiently describe Fujikawa's proposed count. Whether a disclosure contains a sufficient written description to support a proposed count, is a question of fact which we review

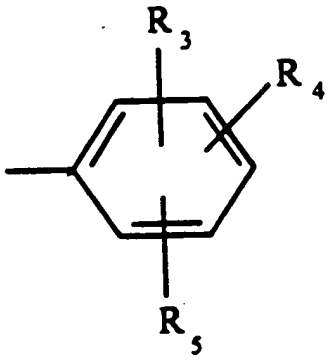
9. This argument, of course, relates only to the compound count, since, as explained above, the method count was not reduced to practice until the *in vivo* testing in December 1987.

for clear error. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed.Cir.1985). We affirm the Board's denial of Fujikawa's motion because we do not believe it was clearly erroneous.

Wattanasin's application disclosed compounds of the following structure:



wherein each of R and R_0 is, independently, C_{1-6} alkyl (primary, secondary, or tertiary), C_{3-7} cycloalkyl, or the following ring,



and each of R_1, R_2, R_3, R_4, and R_5 is, independently, hydrogen, C_{1-4}alkyl, C_{1-4}alkoxy, trifluoromethyl, fluoro, chloro, phenoxy, benzyloxy, or hydroxy.

In addition to this genus of compounds, Wattanasin disclosed as his preferred embodiments that: R_1 and R_2 are most preferably hydrogen, R_0 is most preferably phenyl, 4–fluorophenyl, or 3,5–dimethylphenyl; and R is most preferably methyl [10] or isopropyl.[11]

Essentially, Fujikawa's proposed sub-genus is directed to compounds of the above structure in which R is cyclopropyl [12] and R_0 is 4–fluorophenyl. In other respects, the parties do not dispute that the particular constituents recited in Fujikawa's proposed count are adequately disclosed in Wattanasin's application. Thus, for example, both Wattanasin's most preferred embodiment and Fujikawa's proposed count describe R_1 and R_2 as hydrogen.

In denying Fujikawa's motion, the Board first noted that the proposed sub-genus was not disclosed *ipsis verbis* by Wattanasin. Specifically, the Board noted that Wattanasin preferred methyl and isopropyl for R, rather than cyclopropyl as in the proposed count. In addition, Wattanasin listed three preferred choices for R_0 only one of which was 4–fluorophenyl and gave no indication in his application as to whether he would prefer any one of the choices over the other two.

[19] As the Board recognized, however, *ipsis verbis* disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question. *In re Edwards*, 568 F.2d 1349, 1351–52, 196 USPQ 465, 467 (CCPA 1978). In other words, the question is whether Wattanasin's "application provides adequate direction which reasonably [would lead] persons skilled in the art" to the sub-genus of the proposed count. *Id.* at 1352, 196 USPQ at 467.

Many years ago our predecessor court graphically articulated this standard by analogizing a genus and its constituent species to a forest and its trees. As the court explained:

> It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail ... to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

In re Ruschig, 54 C.C.P.A. 1551, 379 F.2d 990, 994–95, 154 USPQ 118, 122 (1967).

10. Methyl is another name for C_1 alkyl.

11. isopropyl is another name for C_3 alkyl.

12. cyclopropyl is another name for C_3 cycloalkyl.

In finding that Wattanasin's disclosure failed to sufficiently describe the proposed sub-genus, the Board again recognized that the compounds of the proposed count were not Wattanasin's preferred, and that his application contained no blazemarks as to what compounds, other than those disclosed as preferred, might be of special interest. In the absence of such blazemarks, simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses. *See, e.g., id.* 379 F.2d at 994, 154 USPQ at 122 ("Specific claims to single compounds require reasonably specific supporting disclosure and while ... *naming* [each species] is not essential, something more than the disclosure of a class of 1000, or 100, or even 48 compounds is required.").

[20] Before this court, Fujikawa challenges the Board's denial of its motion on two grounds. First, Fujikawa persists in arguing that its proposed count is disclosed *ipsis verbis* in Wattanasin's application. The basis for this contention seems to be that Wattanasin lists cyclopropyl as one possible moiety for R in his disclosure of the genus. Clearly, however, just because a moiety is listed as one possible choice for one position does not mean there is *ipsis verbis* support for every species or sub-genus that chooses that moiety. Were this the case, a "laundry list" disclosure of every possible moiety for every possible position would constitute a written description of every species in the genus. This cannot be because such a disclosure would not "reasonably lead" those skilled in the art to any particular species. We therefore reject Fujikawa's argument on this point.

Second, Fujikawa claims that the Board erred in finding that Wattanasin's disclosure contained insufficient blazemarks to direct one of ordinary skill to the compounds of its proposed count. Specifically, Fujikawa points out that with respect to practically every position on the compound, the proposed count recites at least one of Wattanasin's preferred choices. Even with respect to position R, Fujikawa further explains, one of ordinary skill would have been moved by Wattanasin's disclosure to substitute cyclopropyl for isopropyl because the two substituents are isosteric.

While Fujikawa's arguments are not without merit, we cannot say, on this record, that the Board's decision was clearly erroneous. As the Board pointed out, Fujikawa's proposed sub-genus diverges from Wattanasin's preferred elements at least with respect to position R. Although, in hindsight, the substitution of cyclopropyl for isopropyl might seem simple and foreseeable, Wattanasin's disclosure provides no indication that position R would be a better candidate for substitution than any other. Thus, faced with Wattanasin's disclosure, it was not clear error to hold that one of ordinary skill would not be led to Fujikawa's sub-genus in particular.

Were we to extend *Ruschig*'s metaphor to this case, we would say that it is easy to bypass a tree in the forest, even one that lies close to the trail, unless the point at which one must leave the trail to find the tree is well marked. Wattanasin's preferred embodiments do blaze a trail through the forest; one that runs close by Fujikawa's proposed tree. His application, however, does not direct one to the proposed tree in particular, and does not teach the point at which one should leave the trail to find it. We therefore affirm the Board's denial of Fujikawa's motion.

VI

For the reasons we set forth above, the decision of the Board is, in all respects,

AFFIRMED.